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This is particularly clear since claims 2-15 all depend from the method of claim 1. also, because claims 2-25 are dependent on the method of claim 1, if claim 1 was found to be patentable, then the dependent claims should also be allowable, thus the applicant suggests that no undue burden would be placed on the examiner to examine all the claims together.

Applicants therefore request that the restriction requirement be withdrawn.

## **REQUEST FOR INFORMATION**

The applicant attaches the documents and information requested, including the following documents prepared by the inventor, Dr. James Kaput:

**APPENDIX A**: Response to paragraphs 9, 10, 11 and 13 (examiner's request to provide "explanation of publication's contribution to description of prior art.")

APPENDIX B: Summary of Primary Papers Supporting Patent Application

**APPENDIX C**: Review of Key Publications

Additionally, we enclose copies of two references found during a recent international search by the PCT office (20 September 2004): Elliott et al., 1993; and Rioux et al., 2000.

Due to the relative complexity of this subject matter, the examiner is invited to correspond with the inventor by email, telephone or in person. The inventor's details are as follows:

Jim Kaput 312.829.3036 312.829.3357 (FAX) jim@nutragenomics.com 847.275.6022 (Cell)

The applicant assures the examiner that corresponding directly with the inventor is very effective in dispelling the apparent complexity of the present invention, which is in fact,

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fairly straight forward, once explained in person by Dr. Kaput. We would be happy to set up a conference call or meet the examiner in person.

In response to paragraphs 9, 10, 11 and 13, the applicant supplies the requested documents and information, attached.

In response to paragraph 11 (also see APPENDIX A), no publications or disclosures were relied upon to draft the claimed subject matter. The claims, to the best of our knowledge, cover a completely novel invention. The applicant does, however, provide copies of all the inventor's known relevant scientific papers.

In response to paragraph 12, a prior art search was performed, but nothing of direct relevance was found. Although there are plenty of publications that disclose dietregulated disease-associated genes and that disclose measuring expression profiles in response to stimuli (drugs, food etc), none that the applicant found seem to disclose or suggest the specific invention with the claimed combination of elements, to wit, Claim 1:

A method for identifying diet-regulated disease-associated polynucleotides comprising the steps of:

- (i) selecting at least two different inbred known genotypes (A and B), one of these genotypes (A) being more susceptible to a disease, and the other genotype (B) less susceptible to the same disease;
  - (ii) dividing each genotype into two groups (A1 and A2 and B1 and B2);
- (iii) for each genotype, each group is fed a different diet (A1 is fed diet No.1 and A2 is fed diet No.2, and similarly for B1 and B2);
- (iv)measuring gene expression and comparing expression across the strains that differ in either genotype or in diet, but not in both;
- (v) analyzing the expression data so as to identify diet-regulated disease-associated genes.

In response to paragraph 13 (also see APPENDIX A), the current invention possesses various very important advantages over the prior known methods. Particularly, the method of the invention is unique and useful because it discloses a method that identifies genes regulated by diet, genotype, and genotype X diet interactions. None of the previous methods combine all these elements to effectively identify disease-associated,

diet-regulated genes. Because the current method uses all these factors, as well as using the Quantitative Trait Loci (QTL) information, the current method can identify previously unidentified disease-associated, diet-regulated genes (as shown by the large number of newly identified disease-associated, diet-regulated genes disclosed in the present application.

The applicants thank Examiner Sisson for his consideration, and once again invite the examiner to correspond directly with Dr. Kaput. If this would be helpful, please let me know. Coincidentally, Dr. Kaput will be available and in Washington D.C. on Nov 30<sup>th</sup> and Dec 2<sup>nd</sup>. Please let us know if you would like to meet at that time. Alternatively, we would be happy to set up a conference call.

Respectfully submitted,

Date: 2nd Noom her 2004

Adam Warwick Bell, D.Phil.

Reg. No.: 43,490 Bell & Associates,

416 Funston Avenue, Suite 100,

San Francisco, California 94118

Tel: (415) 752-4085 Fax: (415) 276-6040

abell@bell-iplaw.com